Libby-toxicity

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 2 3 2011

OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

The Honorable Max Baucus
United States Senator
8 Third Street East
Kalispell, Montana 59901

Dear Senator Baucus:

Thank you for your February 2, 2011 letter to U.S. Environmental Protection Agency (EPA) Regional Administrator, James Martin, regarding an inquiry from your constituent, Mr. Gordon Sullivan, on the Berman and Crump protocol for estimating cancer toxicity from exposure to asbestos to develop a risk assessment for the Libby, MT community.

I appreciate the opportunity to respond to your letter, as EPA Headquarters, in partnership with EPA Region 8, is responsible for leading the development of the cancer and non-cancer toxicity values for Libby amphibole asbestos. EPA Region 8 also responded directly to Mr. Sullivan in an August 10, 2010 email from Ms. Sonya Pennock. In that correspondence, it was noted that EPA has had the Berman and Crump protocol – both the Berman and Crump model developed for EPA in 2003 and a subsequent model protocol developed by EPA's Office of Solid Waste and Emergency Response (OSWER) in 2008 – reviewed by independent outside expert panels. Both external scientific reviews, one of which was the Scientific Advisory Board (SAB) Asbestos Committee, indicated significant concerns with the approach as presented. As a result of those concerns, EPA has not used this risk model and we have decided not to pursue further development of this approach at this time.

These reviews were initiated in accordance with agency-wide Peer Review Policy, which encourages and expects peer review of all scientific and technical information that is intended to inform or support agency decisions. This policy specifies that influential scientific assessments should be peer reviewed in accordance with EPA's Peer Review Handbook (US EPA 2004). The peer review process includes a formal record of the conduct of the peer review, including the type of peer review performed and an explanation of how the peer review comments were addressed. More details regarding the expert panels and their findings are enclosed.

In light of the SAB Asbestos Committee's concerns about the Berman and Crump protocol, EPA has decided not to pursue further development of this approach (US EPA Response, EPA-SAB-09-004, December 29, 2008). Instead, EPA is working on a focused effort to estimate the cancer potency of Libby amphibole asbestos. EPA has been examining epidemiology studies of individuals exposed to the Libby Amphibole Asbestos and developing an estimated cancer potency factor and non-cancer reference concentration for use in risk

assessment for the Libby community. EPA is beginning internal reviews of those draft values and will release them for public comment and independent peer review by the Science Advisory Board this year.

We appreciate your interest in EPA's risk assessment work on Libby amphibole asbestos. Again, thank you for your letter. If you have further questions, please contact me or your staff may call Carolyn Levine, in EPA's Office of Congressional and Intergovernmental Relations, at 202-564-1859.

Sincerely,

Mathy Stanislaus
Assistant Administrator

Enclosure

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2003 External Peer Consultation:

Berman and Crump described an approach to predict the cancer toxicity of different types and dimensions of asbestos fibers in a draft report submitted to EPA October 2003. This 2003 draft report was reviewed by an external panel of scientific experts convened by EPA. The panel endorsed the general approach, but a number of technical issues were identified for further evaluation and model development, specifically more transparent presentation of the source data and modeling details so the protocol could be reviewed in detail. In addition, the panel recommended uncertainty analyses and sensitivity analyses to assess model performance. Further detail regarding the review can be found in "Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk" (May 30, 2003: http://www.epa.gov/oswer/riskassessment/asbestos/pdfs/asbestos_report.pdf). A follow-up contractor version of the protocol was developed in 2004, but as it did not address all of the external panel's recommendations, therefore, EPA did not endorse this protocol.

2008 External Peer Consultation:

In response to the expert review panel's recommendations, EPA further developed the work initiated by Berman and Crump, and a revised protocol was taken to EPA's Science Advisory Board (SAB) in 2008 for an independent external scientific consultation. The SAB Asbestos Committee wrote: "The Committee ...generally agreed that the scientific basis as laid out in the technical document in support of the proposed method is weak and inadequate. A primary concern is the lack of available data to estimate the transmission electron spectroscopy (TEM) specific levels of exposure for epidemiological studies utilized in this analysis." The Committee also found that the document was woefully inadequate with respect to the representation of available information on epidemiology, toxicology, mechanism of action and susceptibility. The Committee urged the Agency to "support additional targeted research, exposure data collection and fiber analysis, and validation of alternative risk assessment models." The Committee further stated that the "ongoing research effort focusing on amphibole asbestos exposure in Libby, Montana [is expected to] yield valuable data and insights to further this scientific effort" (US EPA Science Advisory Board correspondence, 14 November, 2008: http://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/f2a5dbfe31ffa9588525701a005896d3!OpenDocument&TableRow=2.0).